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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,567

09/19/2005

Peter Mullejans

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EXAMINER

HAND, MELANIE JO

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

11/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/549,567

Applicant(s)

MULLEJANS ET AL.

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-14 is/are rejected.
- 7) ☒ Claim(s) 11 and 15-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/10/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see Remarks, filed September 17, 2007, with respect to the objection to claim 14 have been fully considered and are persuasive. The objection to claim 14 has been withdrawn.

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Drawings

The drawings were received on September 17, 2007. These drawings are accepted.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6-10 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (U.S. Patent No. 5,591,144).

With respect to **claim 1**: Smith teaches an ostomy appliance comprising: a base plate in the form of flange 3, said base plate having a first hole for receiving a stoma and an adhesive wafer in the form of adhesive layer 4 having a first surface to be attached to the wearer's abdomen, back, or chest (Fig. 5). A receiving member in the form of bag 1 is releasably attached to the base plate 3 via double sided tape 12, said bag 1 having a second hole for receiving wastes exiting the stoma (Fig. 2). A disposable inner bag liner 2 forms a second bag inside the

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receiving member 1. The disposable inner bag liner 2 has a third hole for receiving wastes exiting the stoma and the receiving member 1 is releasably attachable to the base plate 3 by a second coupling component. The first coupling component is in the form of a flange projecting from the rim of the third hole (indicated generally at item 2a in Fig. 2A) and having a surface for sealing via welding against a second surface of the base plate 3 facing away from the user. Inner bag liner 2 has folds along a plurality of folding lines such that said inner bag liner 2 is compacted lengthwise prior to use, said folds being provided between the third hole and a bottom of the inner liner so that, in said compacted condition, an inner surface of said liner bottom is facing and adjacent said third hole, initial wastes exiting the stoma contacting said inner surface of said liner bottom and necessarily forcing said bottom away from the third hole due to associated physical forces applied to the bottom of the bag from the flow of waste. The inner bag liner 2 thus also necessarily unfolds toward a bottom of the receiving member as the liner is filled due to said physical force from the flow of waste from the stoma. (Cols. 4 and 5, all lines)

Smith teaches that inner bag liner 2 is welded to base plate 3 and thus does not teach that the bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling component. However, Smith teaches that welding and double sided adhesive tape are equivalent means for attaching outer bag 1 to the base plate 3 and teaches that bag liner 2, not outer bag 1, is disposed of after a single use, therefore it would be obvious to one of ordinary skill in the art to modify the article of Smith such that bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling component, i.e. the adhesive flange projecting from the rim of said third hole with a reasonable expectation of success to provide quicker releasable attachment of the disposable single-use bag liner 2. The first coupling

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component of the article fairly suggested by Smith has a surface for releasable sealing against a first surface of the adhesive wafer and thus comprises an adhesive flange.

With respect to **claim 2**: The second coupling component is in the form of an adhesive flange 12 of double sided adhesive tape projecting from the rim of the second hole and necessarily having a surface for adhesive sealing against the second surface of the base plate.

With respect to **claim 3**: Smith does not teach that an outer diameter of the first coupling component is greater than an inner diameter of the second coupling component. However increasing the length of said first coupling means (i.e. the flange in the marked Fig. 2A of Smith shown below) such that the outer diameter is greater than the inner diameter of second coupling means 12 would provide more surface area for adhesion of bag liner 2 to base plate 3, thus providing more securement for the bag while in use as the flow of exudates applies force to the bag liner, preventing the bag liner 2 from becoming prematurely detached. It would be obvious to one of ordinary skill in the art to modify the article of Smith so as to lengthen the adhesive flange of bag liner 2 projecting from the rim of said third hole such that the outer diameter of the flange, i.e. the first coupling component, is greater than the inner diameter of second coupling component 12 to provide stronger securement of the bag liner to the base plate to prevent premature detachment of the bag liner during use.

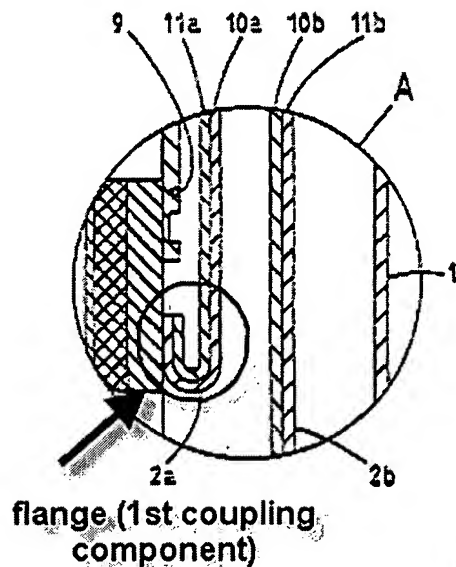


Figure 2A

With respect to **claim 4**: A peel strength of the adhesive sealing of the first coupling component is necessarily greater than a peel strength of the second coupling component, as Smith teaches double sided tape for the second component, which is a releasable means of coupling, whereas Smith teaches welding for the first coupling means, which is a permanent mechanical attachment and thus requires a greater peel strength.

With respect to **claim 6**: The inner bag liner 2 is provided with a membrane comprised of water-impermeable material such as polyvinyl alcohol, which inherently and necessarily allows intestinal gas to escape, as polyvinyl alcohol film is gas permeable, but is impermeable to liquids.

With respect to **claim 7**: Smith teaches an ostomy appliance comprising an adhesive wafer in the form of adhesive flange 3, said adhesive wafer 3 having a first hole for receiving a stoma, said adhesive wafer 3 having a first surface to be attached to the wearer's abdomen (Smith

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refers to flatus gases, which are intestinal gases). A receiving member or bag 1 is attached to the adhesive wafer 3, said bag 1 having a second hole for receiving wastes exiting the stoma. A disposable inner bag liner 2 forms a second bag inside the receiving member, said disposable inner bag liner 2 having a third hole for receiving wastes exiting the stoma. The first coupling component is the form of a flange projecting from the rim of the third hole and has a surface for sealing against a first surface of the adhesive wafer 3 inasmuch as Smith teaches that the bag liner 2 is welded to the wafer 3. Inner bag liner 2 has folds along a plurality of folding lines such that said inner bag liner 2 is compacted lengthwise prior to use, said folds being provided between the third hole and a bottom of the inner liner so that, in said compacted condition, an inner surface of said liner bottom is facing and adjacent said third hole, initial wastes exiting the stoma contacting said inner surface of said liner bottom and necessarily forcing said bottom away from the third hole due to associated physical forces applied to the bottom of the bag from the flow of waste. The inner bag liner 2 thus also necessarily unfolds toward a bottom of the receiving member as the liner is filled due to said physical force from the flow of waste from the stoma.

Smith teaches that inner bag liner 2 is welded to base plate 3 and thus does not teach that the bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling component. However, Smith teaches that welding and double sided adhesive tape are equivalent means for attaching outer bag 1 to the base plate 3 and teaches that bag liner 2, not outer bag 1, is disposed of after a single use, therefore it would be obvious to one of ordinary skill in the art to modify the article of Smith such that bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling component, i.e. the adhesive flange projecting from the rim of said third hole with a reasonable expectation of success to provide quicker releasable attachment of the disposable single-use bag liner 2. The first coupling

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component of the article fairly suggested by Smith has a surface for releasable sealing against a first surface of the adhesive wafer and thus comprises an adhesive flange.

With respect to **claim 8**: Smith teaches that the inner bag liner when compacted lengthwise forms a disc-like structure having an outer diameter. However Smith does not teach that the outer diameter of the disc-like structure is less than the inner diameter of the first coupling component. However, this is achieved by merely changing the placement of the folds. Since the bag liner 2 is limited by its own size and the size of the outer bag 1, there are only a finite number of fold placements that can be achieved such that the liner meets the remaining claim limitations and still fits within the bag. Further, Smith teaches that bag liner 2 is disposable. The task of disposal of bag liner 2 would be made easier by a compacted bag liner 2 whose outer diameter when compacted is less than the inner diameter of the first coupling component and the third hole. This would mean that the bag liner 2 is unobstructed, and this configuration would facilitate easy grasping and pulling of the bag liner 2 out of the outer bag 1 for disposal. It would thus be obvious to one of ordinary skill in the art to modify the article of Smith such that the outer diameter of the disc-like structure of bag liner 2 when compacted has an outer diameter that is less than the inner diameter of said first coupling component so as to provide an unobstructed path for removal and disposal of a used bag liner 2.

With respect to **claim 9**: The folding of said liner 2 along said folding lines forms a bellows.

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With respect to **claim 10**: The folding of said liner along said folding lines results in lengthwise compaction of the bag liner 2, thus necessarily forming a telescopic bellows, as the bag unfolds lengthwise as well.

With respect to **claim 12**: Smith teaches a disposable inner bag liner 2 having an open end receiving effluents or waste products of the body and for use together with an ostomy appliance having an adhesive wafer in the form of adhesive flange 3 to be attached to the wearer's abdomen (Smith refers to flatus gases, which are intestinal gases). A receiving member or bag 1 having a receiving member hole for receiving wastes exiting the stoma. The disposable inner bag liner 2 comprises a liner hole in said open end for receiving wastes exiting the stoma, and has a closed end capable of forming a bag inside receiving member 1. A flange projects from the rim of the liner hole (Fig. 2A) and has a surface for sealing against a first surface of the adhesive wafer 3 inasmuch as Smith teaches that the bag liner 2 is welded to the adhesive flange 3. Inner bag liner 2 has folds along a plurality of folding lines such that said inner bag liner 2 is compacted lengthwise prior to use, said folds being provided between the liner hole and a bottom of the inner bag liner so that, in said compacted condition, an inner surface of said liner bottom is facing and adjacent said liner hole, initial wastes exiting the stoma contacting said inner surface of said liner bottom and necessarily forcing said bottom away from the liner hole due to associated physical forces applied to the bottom of the bag from the flow of waste. The inner bag liner 2 thus also necessarily unfolds toward a bottom of the receiving member as the liner is filled due to said physical force from the flow of waste from the stoma.

Smith teaches that inner bag liner 2 is welded to base plate 3 and thus does not teach an adhesive flange that projects from the rim of the liner hole. However, Smith teaches that welding and double sided adhesive tape are equivalent means for attaching outer bag 1 to the

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base plate 3 and teaches that bag liner 2, not outer bag 1, is disposed of after a single use, therefore it would be obvious to one of ordinary skill in the art to modify the article of Smith such that an adhesive flange projects from the rim of said third hole with a reasonable expectation of success to provide quicker releasable attachment of the disposable single-use bag liner 2. The article fairly suggested by Smith thus discloses a surface for releasable sealing against a first surface of the adhesive wafer and thus comprises an adhesive flange that projects from the rim of the liner hole.

With respect to **claim 13**: The inner bag liner 2 is provided with a membrane comprised of water-impermeable material such as polyvinyl alcohol, which inherently and necessarily allows intestinal gas to escape, as polyvinyl alcohol film is gas permeable, but is impermeable to liquids.

With respect to **claim 14**: Smith teaches a method of applying to an ostomate an ostomy appliance comprising a base plate in the form of flange 3, said base plate having a first hole for receiving a stoma and an adhesive wafer in the form of adhesive layer 4 having a first surface to be attached to the wearer's abdomen. A receiving member in the form of bag 1 is releasably attached to the base plate 3 via double sided tape 12, said bag 1 having a second hole for receiving wastes exiting the stoma (Fig. 2). A disposable inner bag liner 2 forms a second bag inside the receiving member 1. The disposable inner bag liner 2 has a third hole for receiving wastes exiting the stoma and the receiving member 1 is releasably attachable to the base plate 3 by a second coupling component. The first coupling component is in the form of an adhesive flange projecting from the rim of the third hole (indicated generally at item 2a in Fig. 2A) and having a surface for sealing via welding against a second surface of the base plate 3 facing

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away from the user. Inner bag liner 2 has folds along a plurality of folding lines to form a disc-like structure such that said inner bag liner 2 is compacted lengthwise prior to use. The folds are provided between the third hole and a bottom of the inner liner so that, in said compacted condition, an inner surface of said liner bottom is facing and adjacent said third hole, initial wastes exiting the stoma contacting said inner surface of said liner bottom and necessarily forcing said bottom away from the third hole due to associated physical forces applied to the bottom of the bag from the flow of waste. The inner bag liner 2 thus also necessarily unfolds toward a bottom of the receiving member as the liner is filled due to said physical force from the flow of waste from the stoma. Smith inherently and necessarily teaches the steps of locating the stoma and applying the base plate and locating the inner bag liner. (Figs. 5,6) The step of applying and sealing the inner bag liner to the first coupling area is accomplished by the welding of bag liner 2 to base plate 3, as the first coupling area as disclosed includes said base plate 3 (see applicant's Abstract). (Cols. 4 and 5, all lines)

Smith teaches that inner bag liner 2 is welded to base plate 3 and thus does not teach that the bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling component. However, Smith teaches that welding and double sided adhesive tape are equivalent means for attaching outer bag 1 to the base plate 3 and teaches that bag liner 2, not outer bag 1, is disposed of after a single use, therefore it would be obvious to one of ordinary skill in the art to modify the article of Smith such that bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling component, i.e. the adhesive flange projecting from the rim of said third hole with a reasonable expectation of success to provide quicker releasable attachment of the disposable single-use bag liner 2.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (U.S. Patent No. 5,591,144) in view of Wolrich (U.S. Patent No. 5,423,782).

With respect to **Claim 5**: An outer diameter of the first coupling component (the adhesive flange extending from the rim of said third hole) is smaller than an inner diameter of the second coupling component 12.

Smith does not teach that the second coupling component is in the form of one or more coupling rings. Wolrich teaches an ostomy bag having a receiving member in the form of an outer bag and an inner bag liner. Wolrich teaches a second coupling component as disclosed in the form of coupling means 18 comprised of a ring-shaped flange coupling 18 that mates with ring 34, i.e. one or more coupling rings. As can be seen in Fig. 1, the outer diameter of first coupling means 46 is less than the inner diameter of first coupling means 46. Since the structure of the articles of Smith and Wolrich are substantially identical and seek to solve a similar problem in the art (i.e. provide an ostomy waste collector having a bag and an inner liner attachable to a stoma to collect waste therefrom), it would be obvious to one of ordinary skill in the art to modify the article of Smith such that the instant second coupling means (double sided tape) is replaced by the second coupling component of Wolrich to maintain the ability of the article of Smith to releasably attach to a stoma for waste collection and easier disposal.

Allowable Subject Matter

Claims 11 and 15-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for Indicating Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter: A thorough search of the prior art of record did not disclose any reference, alone or in combination with other reference(s) that teaches or fairly suggests the following: with respect to claims 11, 16 and 17, a compacted inner bag liner compacted in the manner claimed in amended claim 7 (i.e. such that the bottom of the bag liner is adjacent the claimed third hole) and provided with a cover. The limitation "to retain the inner bag liner in said compact condition prior to use" is functional language that is given little patentable weight herein. The closest prior art is the Smith reference cited herein and Boehringer et al (U.S. Patent Application Publication No. 2004/0064132). The combination of the Smith and Boehringer references would teach or fairly suggest the claimed invention. However, there is no motivation to combine these prior art devices. Boehringer teaches a bellows device for collecting exudates from a wound site or stoma having a cover to retain such bellows in place, however one of ordinary skill in the art would not be motivated to look to the field of endeavor that the Boehringer device concerns itself with, specifically suction-assisted wound healing. Further the cover of Boehringer does not retain the bellows in a compacted condition, as the very function of the bellows is to assist in the wound collection by expanding in response to suction force applied. The cover merely provides a closed environment for the device and the wound environment. With respect to claim 15, because Smith, either alone or in combination with Boehringer, does not teach or fairly suggest such cover for the inner bag liner, Smith, alone or in combination with Boehringer also does not disclose the method step of securing the claimed disc-like structure in the claimed compact configuration by placing a cover on a closed end of the claimed bag liner, or the step of said cover being removed in use by automatic unfolding of said bag liner.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

November 21, 2007

Tatyana Zelukaeva, Ph.D.
Primary Examiner

A handwritten signature in black ink, appearing to read 'Tatyana', with a long, sweeping horizontal line extending to the right.